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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,062	02/17/2004	Thomas V. Magee	PC11895B	2483

28523 7590 08/31/2006  
PFIZER INC.  
PATENT DEPARTMENT, MS8260-1611  
EASTERN POINT ROAD  
GROTON, CT 06340

EXAMINER
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AULAKH, CHARANJIT

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 08/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/781,062

**Applicant(s)**

MAGEE ET AL.

**Examiner**

Charanjit S. Aulakh

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,8-10,13,14 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 8-10, 13, 14 and 17-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. According to paper filed on June 9, 2006, the applicants have amended claims 1, 9, 10, 13, 17 and 21.
2. Claims 1, 8-10, 13, 14 and 17-22 are now pending in the application.

### ***Response to Arguments***

3. Applicant's arguments filed on June 9, 2006 have been fully considered but they are not persuasive regarding enablement rejection, some indefiniteness rejection, utility rejection and prior art rejection. In regard to enablement rejection, the examiner does not agree with the applicants arguments that no undue experimentation would be required to practice the invention. The applicants have provided various assays for assessing efficacy of instant compounds. However, there is no teaching or working examples present in the specification regarding any animal model of any disease condition where the instant compounds were found to be efficacious either alone or in combination with hundreds of thousands of drugs. The applicants did not provide any references showing well known utility of treating any disease condition of structurally closely related compounds having PDE4 inhibitory activity. As stated clearly in the last office action, in absence of such teachings, guidance, presence of working examples and the state of the prior art, it would require undue experimentation for the full scope of instant claims 18-22.

In regard to indefiniteness rejections of instant claims 18 and 19, the examiner does not agree with the applicants arguments that specification teaches over 35 pages various diseases that are mediated by PDE4 isozyme. There is no single disease known in the

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art which is solely mediated by PDE4 isozyme. The specification merely mentions various disease conditions which may involve PDE4 isozyme as one of the several known etiologies of these disease conditions. The examiner also does not agree regarding the term ---for use--- in claim 19. If claim 19 is directed to pharmaceutical composition only, then applicants are suggested to delete – for use in treating a subject---. As such, the steps involved in the process or method are missing.

In regard to prior art rejection, the applicants have put a proviso to exclude compounds in the cited reference. However, this proviso introduces new matter as will be discussed under new grounds of rejection. In regard to objection of claims for containing non-elected subject matter, the applicants have tried to amend claims to read upon the elected subject matter. However, the independent claim 1 still contains non-elected subject matter since according to elected group I, variables B1 and B2 must represent saturated or unsaturated carbocyclic ring. The instant claim 1 is directed to compounds where variables B1 and B2 comprise saturated or unsaturated carbocyclic ring. The term comprise encompasses heterocyclic ring systems which may have these carbocyclic rings somewhere as variables.

### ***Conclusion***

4. Rejection of claims 18-22 under 35 U.S.C. 112, first paragraph is maintained for the reasons of record.
5. Rejection of claims 18, 18 and 22 under 35 U.S.C. 112, second paragraph is maintained for the reasons of record.
6. Rejection of claim 19 under 35 U.S.C. 101 is maintained for the reasons of record.

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7. Rejection of claims 1, 9, 10, 13, 14 and 17-22 under 35 U.S.C. 102(b) is maintained for the reasons of record.

8. Objection of claims 1, 8-10 and 18-22 for containing non-elected subject matter is maintained for the reasons of record.

NEW GROUNDS OF REJECTION

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1, 8-10, 13, 14 and 17-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In independent claim 1, the applicants have put a proviso that ----.when m is 0, and R7 is C1 alkyl, then R9 is not H, and when m is 0, and R9 is C1 alkyl, then R7 is not H-----. This proviso introduces new matter since it makes a different core which was not described in the original specification. Also, regarding the value of variable A as (1.1.3 ), the instant formula is not described in the specification. According to the specification, formula (1.1.3 ) represents -C(O)-N(R7)(R9)---and not -C(O)-C(R7)(R9)--- and therefore, also introduces new matter.

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11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on (571)272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Charanjit S. Aulakh  
Primary Examiner  
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